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Reporting Vaccine-Associated Paralytic Poliomyelitis: Concordance between the CDC and the National Vaccine Injury Compensation Program

Robert E. Weibel, MD, and David E. Benor, JD

ABSTRACT

This paper compares cases of paralytic poliomyelitis reported to the systems operated by the National Vaccine Injury Compensation Program and the Centers for Disease Control and Prevention (CDC) for reporting of adverse events associated with vaccination. Of the 118 cases of vaccine-associated paralytic poliomyelitis determined by either system, 18 were reported initially only to the compensation program, 50 only to the CDC, and 50 to both. The annual incidence of vaccine-associated paralytic poliomyelitis determined from data from both systems varied from 6 to 13 cases (mean = 9.1) a year, with an increase of 1.4 cases a year when initial reports only to the compensation program are included. Thus, the compensation program provides important supplemental incidence data. (*Am J Public Health.* 1996;86:734–737)

Introduction

The National Vaccine Injury Compensation Program is a federal "no-fault" system to provide compensation for individuals who were injured or who died as a result of specified immunizations. A division of the US Department of Health and Human Services, the program was established under the National Childhood Vaccine Injury Act of 1986 and became effective on October 1, 1988.

For oral poliovirus vaccine cases, the act requires proof that an individual either received a polio vaccine other than inactivated polio vaccine or contracted polio from another person who received oral poliovirus vaccine.[1] The Vaccine Injury Table for oral poliovirus grants the presumption of vaccine causation if the first symptom of paralytic poliomyelitis occurs (1) in a nonimmunodeficient recipient within 30 days, (2) in an immunodeficient recipient within 6 months, or (3) in a vaccine-associated community case without regard to the date of vaccination. If paralytic polio occurs within the time period prescribed above, any complication (including death) is entitled to a presumption of causation.[2] Paralytic poliomyelitis or other conditions can be determined to be caused in fact by the oral vaccine by a preponderance of medical evidence, which is anything that is more than 50% or is more likely than not. In addition to the above medical requirements, a petition filed with the US Court of Federal Claims must meet certain unrelated statutory requirements for compensation.[3]

Since March 21, 1987, federal law has required health care providers to report to the Vaccine Adverse Event Reporting System (VAERS) the occurrence of any condition set forth in the Vaccine Injury Table.[4] The national surveillance system at the CDC learns of suspected cases of poliomyelitis from (1) VAERS, (2) direct voluntary reporting, (3) an enterovirus surveillance system

Robert E. Weibel is with the National Vaccine Injury Compensation Program, Health Resources and Services Administration, Rockville, Md. David E. Benor is with the Office of the General Counsel, US Department of Health and Human Services, Rockville, Md.

Requests for reprints should be sent to Robert E. Weibel, MD, National Vaccine Injury Compensation Program, Health Resources and Services Administration, Parklawn Bldg, Room 8A-46, 5600 Fishers Lane, Rockville, MD 20857.

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operated by the CDC, and (4) the National Vaccine Injury Compensation Program.

The purpose of this study is to determine if the CDC and the compensation program identify the same cases and agree on the diagnosis of vaccine-associated paralytic poliomyelitis. The cases are those that occurred from 1980 through 1992.

Methods

For compensation program cases, physicians review the medical records and affidavits to determine, if possible, the cause of the injury or death. A medical report is sent to a Department of Justice attorney, who prepares a respondent's report based on the medical report and legal qualifications of the petition. This report is filed with the Court of Federal Claims. A special master of the court decides whether the petitioner is entitled to compensation.

Paralytic poliomyelitis is defined by the CDC as a paralytic illness clinically and epidemiologically compatible with poliomyelitis and present 60 days after onset of symptoms unless death has occurred or the follow-up status is unknown. CDC criteria for diagnosis include (1) for recipients, onset of illness 4 to 30 days after vaccine was received, and (2) for contact cases, onset of illness 4 to 75 days after vaccine was fed to a recipient who was in contact with the patient within 30 days before onset of illness. The CDC classification of vaccine-associated paralytic poliomyelitis is based on clinical, epidemiological, and laboratory data, including the identification of isolated polioviruses as vaccine related by molecular methods, including oligonucleotide fingerprinting or partial genomic sequencing. Paralytic poliomyelitis caused by indigenous wild poliovirus was last reported in the United States in 1979; since then, the disease has been associated only with the administration of oral poliovirus vaccine except for five imported cases.[5,6]

When a suspected case of poliomyelitis is reported to the CDC, intensive follow-up is initiated, and the compiled information is reviewed by an independent expert committee of three. When at least two reviewers conclude that the medical evidence demonstrates vaccine-associated paralytic poliomyelitis, the case subject is further classified by the CDC as a recipient or a contact and as being immunocompetent or immunodeficient. All cases of vaccine-associated paralytic

TABLE 1—Paralytic Poliomyelitis 1980 to 1992: Case Reports to the National Vaccine Injury Compensation Program (CP) and the Centers for Disease Control and Prevention (CDC), by Sex and Age Group

	Males, by Age												Females, by Age											
	<1 y				1–6 y				7–69 y				<1 y				1–6 y				7–69 y			
	Total	CP	CDC	CP & CDC	Total	CP	CDC	CP & CDC	Total	CP	CDC	CP & CDC	Total	CP	CDC	CP & CDC	Total	CP	CDC	CP & CDC	Total	CP	CDC	CP & CDC
Recipients																								
Immunocompetent	46	7	8	12	27	0	2	1	3	0	1	0	1	31	4	5	6	15	0	0	0	0	0	0
Immunodeficient	20	3	0	2	5	1	0	4	5	0	0	0	0	10	2	0	5	7	1	1	3	0	0	0
Contacts																								
Immunocompetent	44	0	3	2	5	0	1	1	2	0	17	6	23	30	0	1	1	2	0	3	1	4	0	4	4	8	14
Immunodeficient	8	0	1	2	3	0	0	0	0	0	3	0	3	6	0	0	0	0	0	0	0	0	0	0	2	2	2
Total	118	10	12	18	40	1	3	6	10	0	21	6	27	77	6	6	12	24	1	4	2	7	0	4	6	10	41

TABLE 2—Number of Vaccine-Associated Paralytic Poliomyelitis Cases Reported to the National Vaccine Injury Compensation Program (CP) and the Centers for Disease Control (CDC) Annually: January 1, 1980, to December 31, 1992

Year	CP Only	CDC Only	Both	Total
1980	0	4	2	6
1981	1	9	0	10
1982	1	9	2	12
1983	1	10	2	13
1984	0	4	4	8
1985	1	6	1	8
1986	2	4	3	9
1987	3	2	5	10
1988	1	1	8	10
1989	5	0	6	11
1990	0	1	5	6
1991	2	0	7	9
1992	1	0	5	6
Totals	18	50	50	118

poliomyelitis determined by the CDC and the compensation program were shared. A total of 18 such cases reported only to the compensation program were submitted to the CDC reviewers; of those, 9 were classified as vaccine-associated paralytic poliomyelitis by at least two reviewers, 7 were not, and 2 are under review. One may speculate that these reviewers use different criteria and a standard that is more rigorous than the preponderance standard. However, these 18 cases are included in the analysis.

Results

A total of 118 cases of paralytic poliomyelitis, listed in Table 1, were determined by at least one system to be vaccine associated, with an onset between January 1, 1980, and December 31, 1992. All vaccine recipient and contact case subjects ranging in age from 1 month to 69 years were divided into immunocompetent or immunodeficient categories and grouped by age and sex to include 77 males and 41 females. Males exceeded females by twofold or more in all categories except immunodeficient recipients (with 10 males and 10 females). Cases (including 1 death) among immunocompetent vaccine recipients occurred at less than a year of age in 42 of 46 cases, with onset after the first dose of vaccine in all but 3 cases. Sixteen of 20 immunodeficient recipient cases (including 3 deaths) demonstrated onset after the second, third, or fourth doses and occurred at less than 7 years of age, with 12 of the 20 occurring at less than a year of age with the earliest onset at 2 months. Among contact cases were 44 immunocompetent subjects, including 7 (with 1 death) aged less than a year of age, 6 aged 1 to 6 years, and 31 aged greater than 6 years of age, and 8 immunodeficient contact subjects, including 3 aged less than a year and 5 (with 1 death) aged greater than 6 years.

All 18 cases reported only to the compensation program involved vaccine recipients, while the 50 reported only to the CDC and the 50 reported to both systems included contact subjects as well. In fact, cases reported only to the CDC were mainly contact cases (33 of 50). The two systems classified only two cases differently in this regard.

The annual incidence of vaccine-associated paralytic poliomyelitis determined by both systems, based on the date of onset, are listed by year in Table 2. The 118 case subjects from 1980 through 1992 (13 years) varied from 6 to 13 cases a year, with no significant change in the pattern. The reports only to the compensation program increased the total number of reports from 100 to 118, and these cases increased the annual average by 1.4 from 7.7 to 9.1 cases a year.

Discussion

While underreporting and overreporting are a serious concern, our objective is to predict the true incidence of vaccine-associated paralytic poliomyelitis. Health care providers who administer vaccines are legally required to report adverse events to the Vaccine Adverse Events Reporting System, but there is no penalty for failure to do so.[4] However, owing to the rarity of paralytic poliomyelitis, it is possible that vaccine administrators may not recognize the condition or may have concerns that reporting may somehow increase their potential liability. By contrast, any individual seeking compensation has a strong incentive to report to the compensation program. For vaccines administered on or after October 1, 1988, those wishing to bring a civil action for damages first must have rejected a judgment under the compensation program.

Both systems have similar criteria for determining vaccine-associated paralytic poliomyelitis. The determinations may differ, however, because of the standard of proof used. The compensation program applies a "preponderance of the evidence" standard while the CDC reviewers are more likely to rely on the greater certainty of the medical evidence standard.

Prevots et al. have recently estimated the completeness of reporting paralytic poliomyelitis through the CDC system to be between 94% (92/98) by direct extrapolation and 81% (92/114) by a capture–recapture method.[7] Based on additional data reported to both systems for the 13-year period from 1980 through 1992, including 9 of 18 additional cases classified as vaccine-associated paralytic poliomyelitis by the compensation program and accepted as such by the CDC, the completeness of reporting to the CDC is 92% (100/109) by direct extrapolation and 85% (100/118) by a capture–recapture method. Assuming that the compensation program diagnoses are correct and that the systems are independent, the capture–recapture method would predict a total of 136 cases (50 both system reports × X (unreported cases) = 50 CDC reports × 18 compensation program reports) of vaccine-associated paralytic poliomyelitis during the 13 years between 1980 through 1992, or 10.5 cases a year. Using the capture–recapture method, both systems obtained 87% (118/136) of the predicted cases. These comparisons show that the compensation program results in increased reporting of adverse events actually associated with oral poliovirus vaccine.

The evidence in this report demonstrates that additional cases of vaccine-associated paralytic poliomyelitis are captured by the compensation program, and the consistency of the conclusions suggests that the decisions are correct. Thus, in addition to providing compensation to individuals injured by oral poliovirus vaccine, the National Vaccine Injury

Compensation Program provides data confirming the relative rarity of vaccine-related injuries. □

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